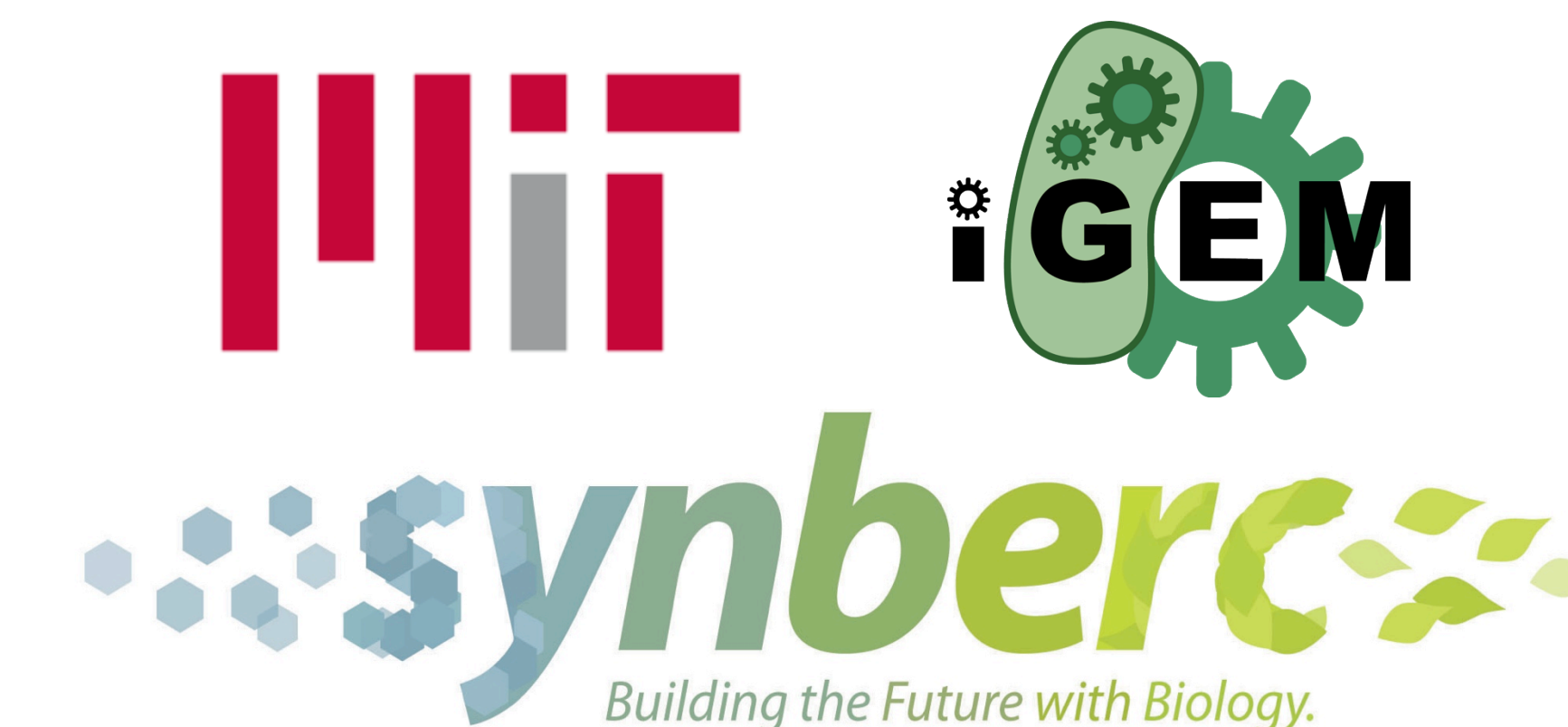


Bridging gaps in regulatory oversight: iGEM as a testbed for proactive risk engagement

Watch for our upcoming paper
in the iGEM special issue of
ACS Synthetic Biology!



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Why does iGEM need a safety program?

- The International Genetically Engineered Machine Competition (iGEM) has grown rapidly. In 2013, 215 collegiate teams from over 35 countries competed, totaling over 3,500 individual participants.
- As project complexity increases, so does the level of potential risk to team members and the public.
- iGEM's fast-paced and exploratory work style challenges the basic approach and timing of institutional biosafety committees / review boards.
- Young scientists, if brought up in a culture of *proactive* and *open* risk engagement, can serve as a defense against both accidental and intentional future harms.

What are some regulatory gaps?

- Different countries have very different biosafety standards.
- The quality of local oversight is not always reliable.
- Most international policies that regulate DNA are based on its organism of origin, not on functional characteristics.
- Even where functional information is taken into account, there is no user-friendly guidance to determine which sequences are regulated or exempt.

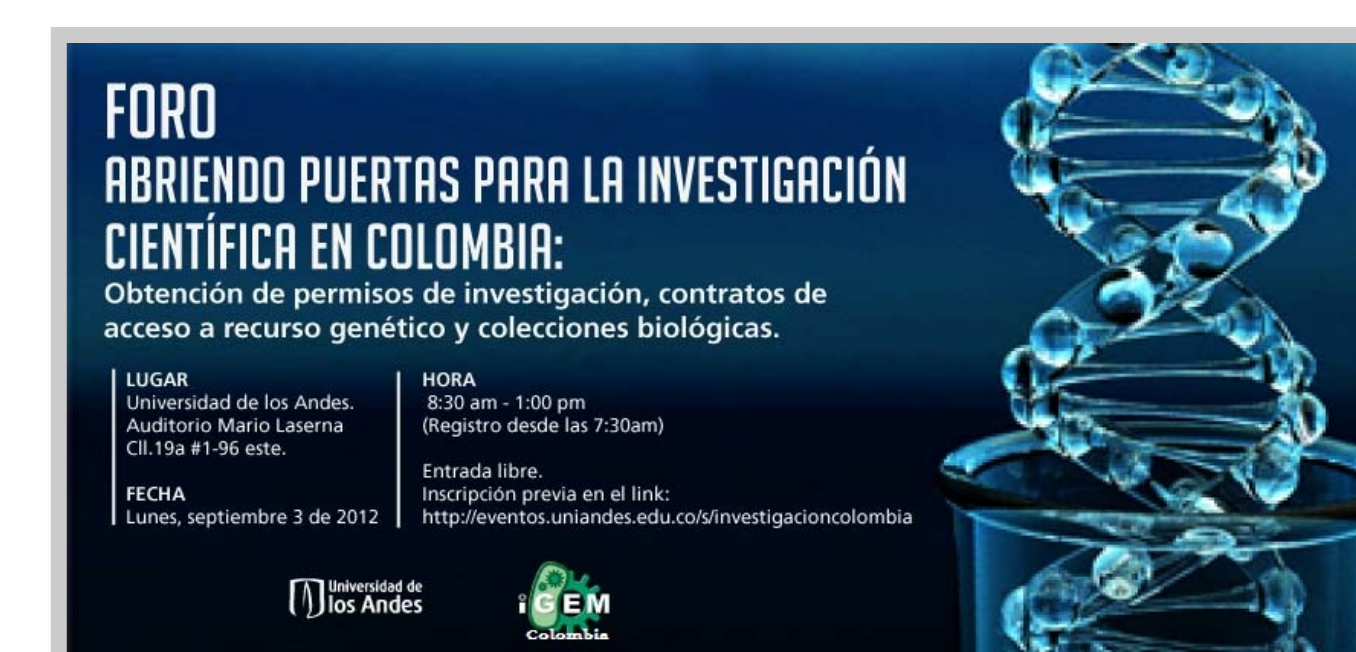
iGEM Teams at the Forefront of Safety



Imperial College London (2011) sought expert feedback, chose a safer chassis, developed a containment device, and wrote guidance on GMO release issues for iGEM teams.



Peking University (2009) tested shipping security by ordering reagents and primers to a private home.



UniAndes Bogotá (2012) held a forum with regulators and scientists to address legal barriers to biological resources access in Colombia.

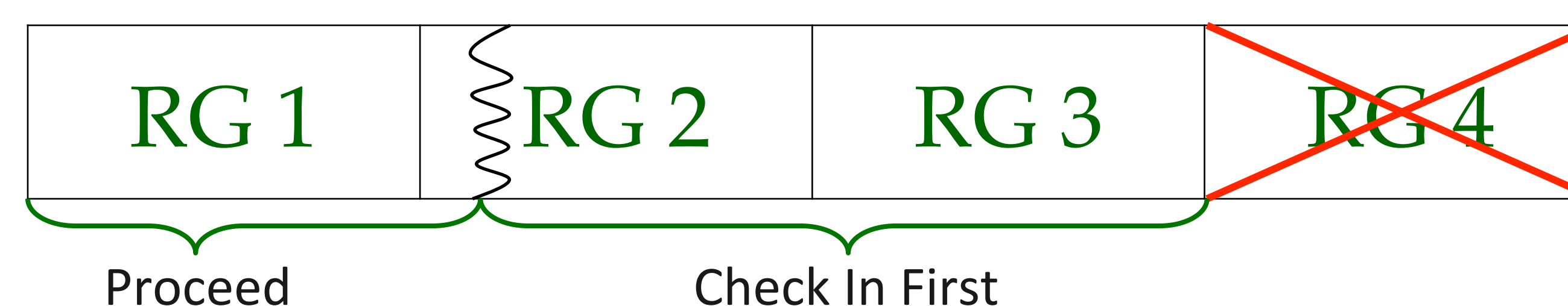


Lethbridge (2013) developed translational frame-shifting elements, and tested the ability of DNA synthesis companies to detect dangerous genes hidden across multiple frames.

2014 Safety Policies

Early and Often – Flexible – Low Barrier to Entry

All teams draft a **Safety Form** early in summer, and finalize in August. Brief **Check-ins** are required before obtaining or using certain materials. Pilot regulations are based on Risk Group (RG) and on *function* of genetic parts. **Consultation** is invited by email and virtual office hours, all season long.



Lessons from Past Years

Prior to 2013, teams answered four open-ended safety questions. Answers varied in quality, and key safety information was obscured.

Use a formal questionnaire as well as prompts for discussion. 2013 safety forms explicitly called out key information, e.g. chassis organism Risk Group.

Safety forms were not due until shortly before the Jamboree, leading to last-minute surprises.

Address safety early in summer. Require check-ins before teams use certain materials.

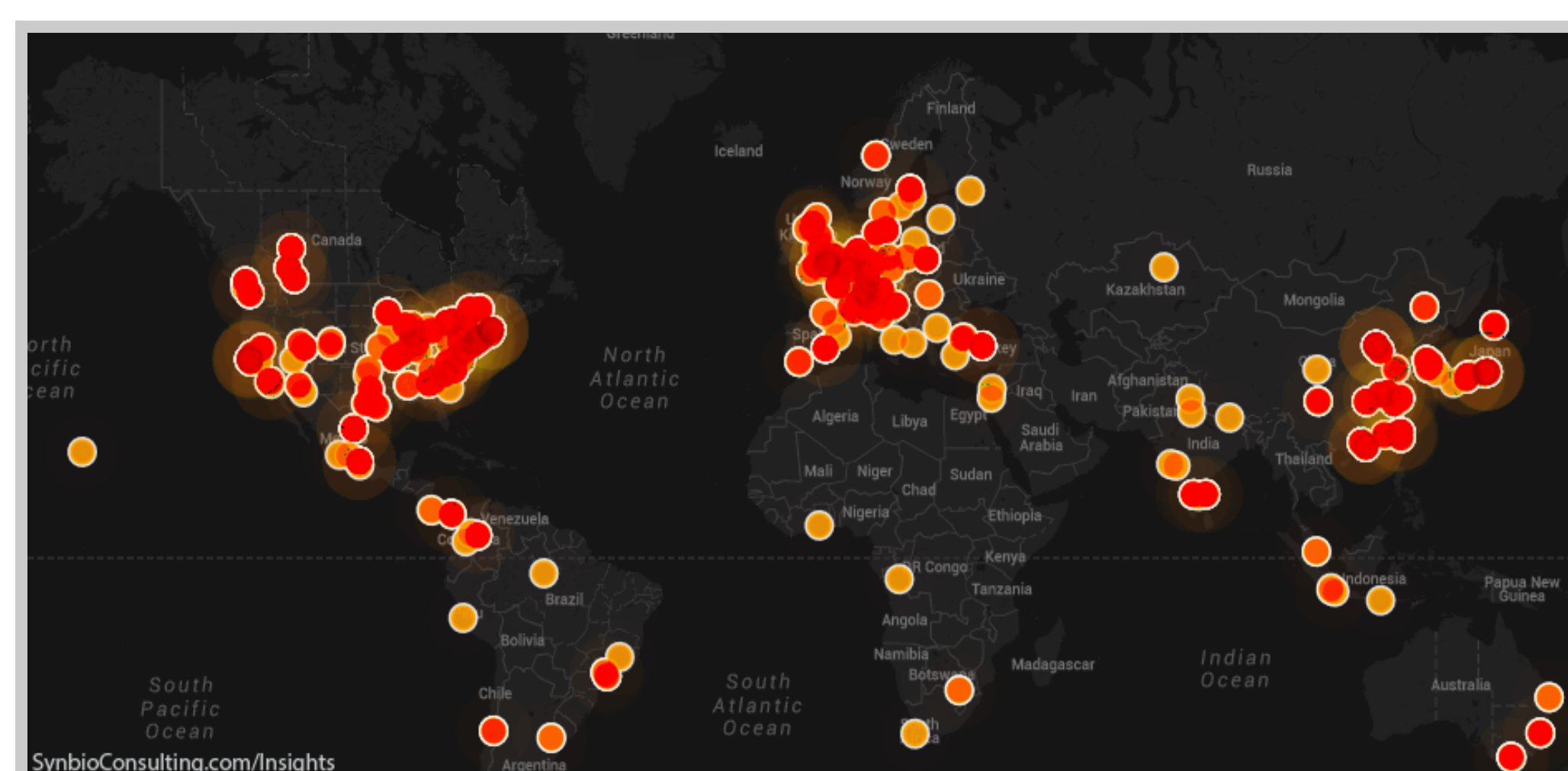
Neither teams nor screeners could easily retrieve safety information about existing Registry parts.

Associate safety information with parts; do not leave it buried in forms. Registry parts were screened by SGI-DNA.

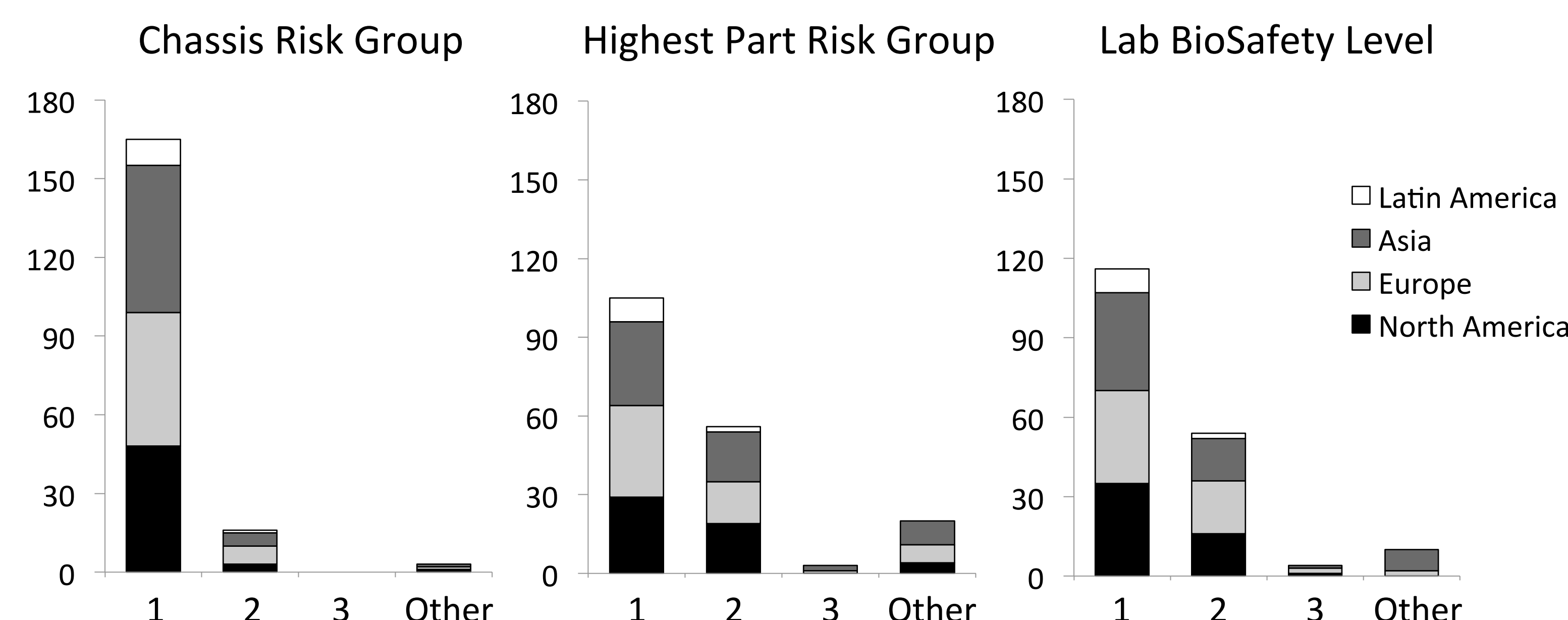
One team, unprompted, asked the Safety committee about their project early in summer, leading to the single biggest safety "catch" of 2013.

Encourage early, informal consultation. Be flexible to accommodate different team schedules.

A Snapshot of iGEM



Global Distribution of Teams



2013 Safety by the Numbers

Thanks to the iGEM Headquarters staff, the Safety Committee, 2013 volunteers Allen Lin and David Lloyd, various iGEM faculty advisors, and Toby Richardson of SGI-DNA. This work was supported by SynBERC and NSF.

Image Sources

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Questions about iGEM?
Leave a sticky note here!
Or email kelly@igem.org

iGEM Safety Committee Members

- ❖ Peter Carr – MIT Lincoln Laboratories
- ❖ Kirsten Jacobsen – Public Health Agency of Canada
- ❖ Tom Knight – Ginkgo BioWorks
- ❖ Todd Kuiken – Synthetic Biology Project, Woodrow Wilson Center
- ❖ Claudia Mickelson – MIT Environment, Health, and Safety Office
- ❖ Piers Millett – United Nations Biological Weapons Convention ISU
- ❖ Kenneth Oye – MIT Program on Emerging Technologies
- ❖ Megan Palmer – SynBERC
- ❖ Anastasia Rogaeva – Public Health Agency of Canada
- ❖ Samuel Yu – Hong Kong University of Science and Technology